

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph appearing on page 14, line 26 through page 15, line 10, with the following amended paragraph:

If an image sensor is utilized, there are many options for displaying the multiple views provided by the invention. Single or multiple displays may be used, with single or multiple views on each display. Options include, but are not limited to those shown in Figures 3. In each scenario, the display may also convey other information such as status of built-in surgical tools, status of the articulation, or readouts from vital signs monitors for example. Fig. 3A illustrates having multiple views (1) and (2) arranged on a single display. The views may take on any shape and do not need to be of equal size. Fig. 3B shows multiple views ~~(1) or (2)~~ (101) or (102) that are accessed on a single display by toggling between the views as needed. In another preferred embodiment of the present invention, a multiplicity of displays may provide visual access to a multiplicity of views. Each display may contain one or more views that can be accessed simultaneously, singly, or by toggling between views. Zero or more of the displays may also show status indicators or other information. As shown in Fig. 3C, one display is showing ~~view (1)~~ view (101) individually, a second display is toggling between views ~~(2) and (6)~~ (102) and (106), and the third is presenting views ~~(3), (4), and (5)~~ (103), (104), and (105), simultaneously with status ~~indicators (7)~~ indicators (107).

Please replace the paragraph appearing on page 19, lines 6-10, with the following amended paragraph:

Looking now at Fig. 8A, the distal portion of the device of the invention is schematically shown. This portion comprises a fixed, non-bending section, indicated ~~at 2~~ at 202 (wherein is located the stapler ejector and the objective optics of the “stapler view” optical channel), and an articulating ~~section 3~~ section 203, and the distal ~~end 4 and 204~~ of length “ ℓ ”.

Please replace the paragraph appearing on page 19, lines 12-21, with the following amended paragraph:

Articulating ~~section 3~~ section 203 is similar in design to that of conventional endoscopes, but possesses several unique features. In order to simplify the alignment procedure and at the same time achieve maximum accuracy, a one-way articulation design has been chosen. This means that the articulating section is constrained to move in one direction only (i.e. the tip of the endoscope can only move from straight ahead to one side). Secondly, the device must be able to bend further than conventional endoscopes in order to carry out the required medical procedure. Finally the articulating section must be strong enough to provide a significant force against the tissues during fundus distension and stapling.

Please replace the paragraph appearing on page 19, lines 23-28, with the following amended paragraph:

The fixed ~~section 2~~ section 202, contains the stapler cartridge. The stapler ejector has a side shooting design and requires an anvil, which is located on the end of the distal tip. Both the stapler cartridge and the anvil module are replaceable and fit into pockets on the shaft and distal tip. These pockets are labeled ~~1 and 1A~~ 201 and 201A respectively in Fig. 8A. The stapling elements at ~~1 and 1A~~ 201 and 201A, together, form the entire stapling assembly.

Please replace the paragraphs appearing on page 20, line 1 through page 21, line 10 with the following amended paragraphs:

Fig. 8B shows the device of Fig. 8A in a fully bent position. The articulation ~~section 3~~ section 203 has been bent through bending angle ϕ using fixed radius of curvature r . The values of radius r and the length L (Fig. 8A) are determined by the fixed values ℓ (length of the rigid distal tip) and y (the distance from the stapler cartridge to the junction of the fixed and bending portions of the distal end of the endoscope) in such a way that bending the device completely brings the two parts of the stapler assembly exactly into alignment.

Exact alignment is accomplished by deploying the locking pins to hold the endoscope in the position shown in Fig. 8B during the surgical procedure. In a preferred embodiment of the

invention, locking pins are stored in the anvil section of the stapler. By using an activator (~~shown at 1~~ shown at 302 in Fig. 10), the physician can deploy the pins through the tissue of the fundus and esophagus walls and engage sockets in the staple ejector module. The method of deploying the locking pins is well known to the man of the art and will therefore not be discussed here for the sake of brevity.

Positioning markings ~~4 may~~ 204 ~~maybe~~ located on the device (as indicated in Fig. 8A), at the extremity outside the patient, to provide information on the length of device that has been introduced into the patient.

In order to see both sides of the staple as it is placed, and to assure proper joining of both fundus and esophageal tissues, a preferred embodiment of the invention employs the use of two optic channels (Fig. 9A). In this embodiment, an objective lens 1 captures the image from the tip of the scope (the "distal view"). A flexible fiberoptic image ~~guide 2~~ guide 205 carries the image about 12cm proximally where it is focused by a coupling ~~lens 6~~ lens 8 onto a CCD ~~sensor 8~~ sensor 7. This view fills the main part of the video monitor (~~1 in~~ 401 in Fig. 11), and is always displayed, since it is used during insertion, distention, and stapling. A "stapler view" (~~2 in~~ 402 in Fig. 11) is simultaneously projected onto one corner of the CCD and thus appears in one corner of the monitor. This is a view from the endoscope shaft, looking sideways from the vicinity of the stapler, which is located at ~~position 5~~ position 206 in Fig. 9A. The optical path of this image starts with an object perpendicular to the axis of the endoscope. The optical path travels through the stapler ~~backstop 3~~ backstop 207 and clear portions of the stapler module and with the aid of right angle ~~prism 4~~ prism 208 and objective ~~lens 7~~ lens 1 an image is produced on the ~~CCD 8~~ CCD 7. This view may only be activated during the stapling process. After stapling, the distal view shows the closed staple(s) from the stomach side, and the stapler view shows the staple(s) from the esophageal side. These multiple views provide confidence that each staple is properly placed before repositioning the instrument for the next shot.

Please replace the paragraph appearing on page 21, lines 16-18 with the following amended paragraph:

Fig. 9B is a cross-sectional view of the optical system of Fig. 9A taken at A-A, looking toward the proximal end of the endoscope, showing how the various optical elements are arranged within the sheath of the ~~endoscope~~ endoscope 200.

Please insert the following new paragraph on page 21, following line 18, as follows:

Fig. 9C shows a preferred embodiment of the invention in which endoscope 200 comprises an anvil portion 501A of a stapling device located in pocket 201A, next to the objective lens 1 of a first optical channel on its distal tip. Endoscope 200 further comprises articulation section 203 and non-bending section 202, in which is located the staple-firing portion 501 of the stapling device in pocket 201 next to an objective lens 1 of a second optical channel.

Please replace the paragraph appearing on page 21, lines 20-23 with the following amended paragraph:

Fig. 10 shows the distal tip of the endoscope. The anvil module of the stapler assembly goes into the ~~socket~~ socket 201A. An actuator for locking pins that are contained in the anvil is shown at ~~2~~ at 302. A channel for suction or irrigation is shown ~~at 5~~ at 305. The image channel is ~~4~~ and 3 ~~304 and 303~~ represents illumination fibers.

Please replace the paragraphs appearing on page 22, lines 3-6, with the following amended paragraph:

The display may incorporate status indicators relating to the various functions of the endoscope. For example in Fig. 11, ~~3~~ shows 403 shows the status of the articulation of the distal end, ~~4~~ shows 404 shows the rotation of the endoscope around the long axis, and ~~5~~ shows 405 shows the stapler status.

Please replace the paragraphs appearing on page 22, line 27 through page 24, line 18 with the following amended paragraphs:

The mechanical operation of the device involves the bending of the articulation section of the device so as to engage the fundus of the stomach with the distal tip, and to move it toward the lower esophagus. This is schematically illustrated in Figs. 12(A, B, and C). In Fig. 12A, two positions of the device are shown, a and a'. Position a' is the initial position after the device has been inserted through the mouth and esophagus of the patient to the desired position. Position a illustrates the beginning of bending of articulation section of the device, towards the ~~fundus~~ fundus 209, the tip being indicated as ~~as~~ as 204.

In Fig. 12B, the bending of the device has proceeded to the stage in which the distal ~~tip~~ tip 204 has encountered the wall of the ~~fundus~~ fundus 209 and started to pull it towards the lower region of the esophagus.

In Fig. 12C, the situation shown is that in which bending of the device has been completed, and the distal ~~tip~~ tip 204 has caused the ~~fundus~~ fundus 209 to move from its original position to a position near the lower esophagus 210. In this position, the fundus is correctly positioned by ~~tip~~ tip 204 and it is possible to carry out the stapling together of the fundus and esophagus.

Fig. 13 is a more detailed view of the situation depicted in Fig. 12C. Here is schematically shown the alignment between the staple ~~cartridge~~ cartridge 501, mounted on the endoscope ~~shaft~~ shaft 200 within the ~~esophagus~~ esophagus 210, and the ~~anvil~~ anvil 501A mounted on the distal ~~end~~ end 204 within the ~~fundus~~ fundus 209.

In order to fasten the lower part of the ~~fundus~~ fundus 209 (Fig. 13) to the lower part of the ~~esophagus~~ esophagus 210, by means of the stapling assembly, it is imperative that ~~element~~ element 501 and ~~element 1A~~ element 501A be brought into the correct working positioned relationship, so that the staples, when ejected, perform their required task. Failure to bring the parts of the stapling assembly into the correct positioned relationship may be fatal, as it will result in the staple not being correctly positioned or folded, and in a high risk of damaging the tissue where the stapling has been performed.

As described above, the design of the device assures proper alignment. The surgeon is able to verify this alignment, as well as the proper distention of the fundus towards the esophagus, by using the visual means provided at the distal tip of the endoscope. Further, as the two parts of the stapler are pressed together, the tissue is pressed between them and it is possible to see through the tissue using the visual means provided on the cartridge side. Final alignment is accomplished by deploying the locking pins that are provided in the anvil section of the stapler. Figs. 14 shows the relevant part of the device and tissue. In Fig. 14A, the locking pins (collectively indicated at ~~11~~at 211), that were stored in the anvil ~~assembly 1A~~assembly 501A, have been deployed through the tissue of the fundus and esophagus walls and have engaged the sockets in the stapler ~~cartridge 1~~cartridge 501. The locking pins not only perform the final alignment, but also increase the clamping force during the stapling which is now carried out.

Fig. 14B shows the situation after the stapling has been effected. Staples, (collectively indicated at ~~10~~at 212), have engaged between the fundus and the esophagus, at the specific location on which it was operated. After carefully inspecting the staples the surgeon has retracted the locking pins. The surgeon next straightens the endoscope, and moves the device by rotating it to its next location. When the next location is reached, the bending/aligning procedure is repeated, and the stapling is effected again.